

### REMARKS/ARGUMENTS

Claims 1-3 and 6-10 are now pending, a total of 8 claims. Claims 1 and 9 are independent. Claims 1-3 and 6-10 are objected to because of the following informalities: claims 1 and 9 recite "the syringe barrel." Claims 1-3 and 6-10 have been rejected under 35 U.S.C. § 103(a).

New dependent claim 11 has been added to the application.

Applicant respectfully requests reconsideration of the application.

The informalities objected to have been corrected. The amendments relating to the syringe "barrel" merely clarify the meaning of the claims, and are not made to narrow their scope or for any substantial reason related to patentability.

The corrected drawings identify the "first diameter" and "second diameter" of the invention with reference numbers 15 and 16 in Fig. 2. No new matter is presented.

Applicant believes that the amended claims, and new claim 11, have sufficient antecedent basis for all terms used therein, and that they particularly point out and distinctly claim the subject matter of the invention. As shown below, the amended claims, and new claim 11, are not anticipated, taught, or suggested by any of the cited references.

#### **I. Summary of Record of Interview**

On January 5, 2004, Applicant conducted a telephonic interview with the Examiner. The participants were Examiner Emmanuel Sayoc, and Leslie M. Spencer of Willkie, Farr & Gallagher LLP, on behalf of the Applicant. No exhibits were shown and no demonstration conducted.

## II. Claims 1-3 and 6-10

Claims 1, 3 and 6-10 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Trull et al. (U.S. 6,080,136) in view of Ito (U.S. 5,063, 025).

Claim 2 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Trull et al. (U.S. 6,080,136) and Ito (U.S. 5,063, 025), as applied to claim 1, and in further view of Akaike et al. (U.S. 5,061,247).

**Claim 1:** A gasket for a pre-filled syringe, the syringe comprising a barrel into which liquid is charged,

wherein a peripheral side surface of the gasket that is in contact with an inner surface of the syringe barrel is provided with a restriction, and wherein a periphery of a bottom surface of the gasket that is not in contact with the liquid is formed into a tapered slant, and wherein one or both of the peripheral side surface that is in contact with an inner surface of the syringe barrel and a surface of the gasket that is in contact with the liquid is laminated with polyethylene fluoride resin.

Figure 6 of Trull et al. was cited as disclosing a syringe (70) wherein a peripheral side surface (80) of the gasket is in contact with an inner surface of the syringe barrel (60), wherein a restriction is provided and a periphery of a bottom surface of the gasket that is not in contact with the liquid is formed into a tapered slant. The Examiner has acknowledged that the Trull et al. device differs from the claimed invention in that there is no disclosure of a surface of the gasket having polyethylene fluoride resin as a laminate.

Ito was cited as disclosing that a syringe gasket is commonly coated with a thermoplastic resin such as polyethylene to eliminate the need for a lubricant and serve as a protective coating for the gasket. Ito teaches a "linear plunger made of superelastic wire" (column 3, line 32-34, and claims 1-8) that is used in "an analytical microsyringe [for] gas chromatography and liquid chromatography." (Column 1, lines 7-9.) "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). *Accord In re Clay*, 966 F.2d 656, 23 USPQ2d 1058 (Fed. Cir. 1992) (reference that taught a different structure for a different purpose under different temperature and pressure conditions was not reasonably pertinent to the problem with which the inventor was concerned).

The Ito microsyringe is used in handling non-oxidizable acid, such as hydrochloric acid or sulfuric acid, or other liquids that can destroy or corrode the plunger surface. (Column 4, lines 44-54.) The protective coating layer of Ito's invention prevents the surfaces of the plunger from being destroyed or corroded and thereby retains tight contact between the opposed surfaces of the syringe and plunger. Further, the Ito liquid (or gas) samples are of different composition and viscosity than the contrast medium that is charged into the Trull et al. device or the pre-filled syringe of the present invention.

In addition, the purpose of Ito's microsyringe is to inject "precisely a minute amount" of a gaseous or liquid sample into an analytical apparatus. (Column 1, line 41.) The amount of liquid charged into the Ito microsyringe is very small, not 10 to 200 ml as may be pre-filled in the syringe of the present invention.

Akaike et al. is cited as disclosing that a hardness of JIS of 20-85 is optimal for gaskets applied to syringe devices. No motivation to combine any of the three references -- Trull et al., Ito or Akaike et al. -- has been shown. *Ex parte Skinner*, 2 USPQ2d 1788 (Bd. Pat. App. & Inter. 1986). Applicant respectfully submits that amended Claims 1 and 9, dependent Claims 2, 3, 6, 7, 8 and 10 are patentable over Trull et al., Ito and/or Akaike et al.

### III. New Claim 11

New multiple dependent claim 11 is patentable with the independent claims discussed above. In addition, claim 11 recites additional features that further distinguish the gasket of the present invention from the prior art.

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In view of the foregoing, Applicant respectfully submits that the claims are in condition for allowance. Applicant requests that the application be passed to issue in due course. The Examiner is urged to telephone Applicant's undersigned counsel at the number noted below if it will advance the prosecution of this application, or with any suggestion to resolve any condition that would impede allowance.

Enclosed herewith is a Request for Continued Examination (RCE) as well as a  
Petition for Extension of Time for three (3) months.

Respectfully submitted,

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